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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,214	04/28/2005	Michael J. Detke	X-16031	9490

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,214	DETKE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-28-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A Preliminary Amendment filed April 28, 2005 is acknowledged. Updated priority information is noted. Claims 1-3 are canceled. New claims 5-7 are presented. Accordingly, claims 4-7 are now under consideration.

A complete list of all copending and related applications of David J. Goldstein is requested when responding to this Office Action.

The disclosure is objected to for the following informalities: In claim 5 "a" is omitted after "treating". In claim 6 "ileitis" is spelled incorrectly.

Appropriate correction is required.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention. The claims are directed to the treatment of various gastrointestinal disorders, such as inflammatory bowel disease, functional bowel disorders, dyspepsia, ileitis, ischemic bowel disease, irritable bowel disease, gastroesophageal reflux and diarrhea comprising administering duloxetine. The specification provides support for treating irritable bowel syndrome comprising administering duloxetine. Attention is directed to *In re Wands*, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation.

These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treatment of almost any type of gastrointestinal disorder in that claim 6 recites both specific disease states, as well as signs and symptoms of many others. Given their broadest interpretation, according to The Merck Manual, claims 5 and 6 are drawn to a plethora of pathologies.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the area of gastroenterology.

Each particular type of gastrointestinal has its own specific characteristics and etiology. The broad recitation "treating gastrointestinal disorder" is inclusive of many conditions that presently have no established successful therapies. A successful treatment modality for one particular type of gastrointestinal disorder, such as that which follows microbial infection in ileitis, for example, does not presage success for treating

another type of gastrointestinal disorder, such as cancer, characterized by diarrhea or dyspepsia.

The breadth of the claims

The claims are very broad and inclusive of disorders of diverse etiology.

The amount of direction or guidance provided and the presence or absence of working examples

The working example, Example 1, pages 6-7 in the specification, discloses the administration of duloxetine to treat irritable bowel syndrome. No guidance is provided to treat any other type of gastrointestinal disorder. The prior art discloses the utility of duloxetine for the treatment of gastroesophageal reflux disease.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to treatment regimens for the recited pathologies, i.e., inflammatory bowel disease, functional bowels disorders, dyspepsia, ileitis, ischemic bowel disease and diarrhea. The skilled artisan would expect the interaction of a particular compound in the treatment of a particular type of gastrointestinal disorder to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for the administration of duloxetine. The instant specification sets forth no such understanding. No direction is provided to distinguish therapy among various types of gastrointestinal disorders that are encompassed in the language of the claims. Absent reasonable *a priori* expectations of success for using duloxetine, one skilled in the gastroenterology art would have to test extensively many gastrointestinal disorders to discover which

particular condition responds to a therapeutic regimen with duloxetine. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Considering the state of the art, a disclosed by The Merck Manual and the lack of guidance provided by the specification, one of ordinary skill in the gastroenterology art would be burdened with undue experimentation to treat all forms of gastrointestinal disorders comprising administering duloxetine.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Kamm, M. A., WO 02/062324.

Kamm teaches pharmaceutical compositions comprising duloxetine to treat gastrointestinal disorders characterized by esophageal motility disorders, as well as gastroesophageal reflux disease. See page 6, line 11, as well as claim 42 on page 13. Further, a chemical compound and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, duloxetine cannot presently have mutually exclusive properties. MPEP 2112.01. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

February 10, 2006

Phyllis Spivack
1614

PHYLLIS SPIVACK
PRIMARY EXAMINER